UNIVERSITY OF LEICESTER

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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

The Human Tissue Act (HT Act) and the HTA require a robust system of management and maintenance of all equipment that is used throughout the acquisition and processing of human tissue (from collection through to disposal).

The term equipment used in the context of human tissue may include, but not be limited to:

- Refrigerators and freezers
- Centrifuges
- Incubation systems
- Dewars
- Analysers
- Safety Cabinets
- Microtomes

The HTA expects the equipment life cycle in terms of acquisition, use and disposal to be managed in a planned manner to reduce the risks of equipment failure which may impact on the integrity of tissue samples. It is required that all relevant equipment be subject to quality assurance processes (evidenced by appropriate records), including but not limited to:

- Calibration records
- Scheduled cleaning and decontamination
- Planned basic maintenance
- Preventative maintenance contracts (where appropriate)
- Contingency plans for equipment failure
- Documented reporting process for equipment failure
- Adverse events reporting
- Risk Assessment

Purpose and Scope

The purpose of this SOP is to provide staff and students with guidance on the required standards for the management and maintenance of equipment related to

the use of human tissue in research. This SOP should be read and used, in conjunction with the HTA Codes of Practice for Research.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HT Act	Human Tissue Act
HTA	Human Tissue Authority
PD	Persons Designated
PI	Principle Investigator
REGI	Research Governance Ethics and Integrity
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UEIC	University Ethics and Integrity Committee
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment to establish systems in place to comply with the HTA codes of practice.

It is the responsibility of the HTA Monitoring officer to ensure this SOP remains fit for purpose taking into consideration any changes in legislation and any changes to the HTA codes of practice for research.

It is the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and requirements outlined in this SOP.

All researchers, Chief / Principal Investigators (CI/PIs) involved in using relevant material as part of an ethically approved Research Tissue Bank (RTB), as part of a University Ethics and Integrity Committee approved project (UEIC), and material from external organisations including relevant material that has been sourced from overseas, must comply with the HTA Codes of Practice.

Procedure to follow

This SOP will outline the procedure to follow for the routine maintenance and calibration of equipment that is required to ensure both the longevity of the

equipment and that the equipment is maintained in the best condition so that the integrity of the samples used on those pieces of equipment is maintained (where appropriate), and the data generated are robust.

Routine maintenance

All equipment used in the process of collecting, using, storing and disposal of human tissue should be subject to regular, planned maintenance. The requirement of the maintenance will usually be defined by the supplier of the equipment and should be documented whenever this is performed. Evidence of scheduled maintenance must be available for internal audit or inspection by the HTA. Examples of routine maintenance are:

- Cleaning
- Decontamination
- Defrosting
- Air Filter Checks
- Functional Checks

For freezer maintenance and management please refer to *SOP HTA-A1009* and the corresponding appendices.

Routine Calibration

Equipment (in particular centrifuges) used to prepare, and store human tissue must be subject to routine calibration. This is particularly important for equipment used to render the material acellular. If there is any uncertainty about whether a specific process renders tissue acellular then further guidance and advice can be obtained from the HTA Monitoring Officer.

This is to ensure centrifugation methods remove cells from the sample(s) efficiently, as any samples with resulting cellular material remaining, fall under the remit of the HTA licence.

Maintenance Contracts

Where equipment is critical for the use or storage of human tissue, a maintenance contract should be in place to ensure that a program of planned, preventative

maintenance is in place. Inspection dates should be scheduled and monitored accordingly.

Equipment Failure

Human tissue samples being used for scientific research should be stored under conditions that preserve their integrity through the life cycle of the sample(s) existence. Contingency arrangements should be in place for the failure of critical equipment and such arrangements should be documented in a SOP, and back-up processes and equipment should be available.

Fridge and Freezer Failure

There must be local contingency processes in place that detail the actions to be taken in the event of failure of a temperature-controlled storage unit. Each storage unit containing relevant material should be labelled with an identifier name, name of the PI and contact information in the event of a failure in line with *SOP HTA-A1023*.

Human tissue samples from a failed unit should be relocated to a designated contingency storage facility. The human tissue moved to a contingency storage unit should be labelled with the appropriate information for its duration of storage within the contingency freezer. Contingency freezers containing human tissue should be locked while in use to ensure security of the tissue within the freezer. All storage usage failures should be reported to the HTA adverse events (refer to *SOP HTA-A1022*), and the CI/PIs of the implicated studies should be informed. Immediate arrangements should be made for the repair or replacement of the related equipment. Relevant checks of correct operation should be made and documented before the repaired equipment is used again.

Failure of other Equipment

Failure of equipment not considered to be critical to the integrity of human tissue (e.g. equipment that has an impact on health and safety) should be reported to an appropriate member of staff immediately (e.g. PI, Laboratory Manager, Technical Services Manager) and dealt with as per departmental procedures.

Adverse Events

Equipment-related adverse events should be reported in accordance to *SOP HTA-A1022-UoL*. Examples of events are:

- Storage unit failure.
- Damage to critical equipment e.g. centrifuges, freezers etc.
- Incorrect operation of critical equipment leading to loss of sample integrity.
- Failure to adhere to maintenance schedules.

Clear record systems must be in place to ensure that all adverse events are recorded, and action taken as appropriate. For adverse events and incidents, please refer to *SOP HTA-A1022-UoL*.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N